

### **REMARKS/ARGUMENTS**

Claims 57-63 and 65-69 are pending in the present application. Claims 57-63 and 65-69 are rejected. Applicant respectfully requests reconsideration of these claims in view of the arguments presented herein.

#### **Rejections under 35 U.S.C. § 103(a)**

Claims 57-63 and 65-69 are rejected under 35 U.S.C. § 103(a) as unpatentable over Erickson (US Pat. No. 3,751,569, hereinafter referred to as "Erickson"), Miettinen *et al.* (US Pat. No. 5,502,045, hereinafter referred to as "Meittinen") and Wester *et al.* (WO 99/56558, hereinafter referred to as "Wester.")

Erickson specifically **teaches away from using more than 10% of a sterol fatty acid ester composition in an oil** because of problems with clarity at levels above 10%. Specifically, Erickson states:

**A 10% upper limit has been chosen herein as a practical upper limit and because when used in amounts in excess of that limit most plant sterol ester come out of solution in oil at refrigerator temperatures....** Many of the plant sterol monocarboxylic acid ester additives of this invention are not soluble in oil compositions at refrigerator temperatures at levels less than the above 10% upper limit.... **Most or all of the plant sterol monocarboxylic acid ester additives of this invention are soluble in oil at refrigerator temperatures at and below the maximum preferred limit of 3%.** (Emphasis added.)

Erickson, column 2, lines 35-39, 45-48, and 54-57. Erickson clearly points away from adding **more than 10% of a sterol fatty acid ester composition to an edible oil**, as claimed by Applicants. Not only does Erickson say that 10% is the practical upper limit because levels above that adversely affected the clarity of the edible oil, Erickson goes on to give a **maximum preferred limit of 3%**, because "[m]ost or all of the plant sterol monocarboxylic acid ester additives of this invention are soluble in oil at refrigerator temperatures at and below" that level. One of ordinary skill in the art, reading Erickson, would not be motivated to add more than 10%

and up to 30% of a sterol fatty acid ester composition to an edible oil if they wanted that oil to be clear. From reading Erickson, there would have been no reason to believe that one could make a clear oil containing more than 10%, much less up to 30%, of a sterol fatty acid ester. The Federal Circuit has repeatedly recognized that proceeding contrary to the accepted teachings in the art represent “strong evidence of unobviousness.” In re Hedges, 783 F.2d 1038, 1041 (Fed. Cir. 1986).

Miettinen, while teaching the use of plant sterol fatty acid esters, at levels of up to 13% by weight in example 2-3 and 10-20% by weight in example 2-5, can be easily distinguished from Applicants’ claimed oils. In each of the examples cited, the result was not a clear oil. Example 2 uses up to 13% sterol fatty acid esters in a mayonnaise. Example 5 uses 10-20% sterol fatty acid esters in a margarine. Neither margarine nor mayonnaise are clear. The clarity of the oil does not matter when used in margarine or mayonnaise. Because the only time these higher levels of plant sterols are used is when they are in such things as margarine or mayonnaise, the only inference that can be drawn is that they are added to the margarine or mayonnaise specifically because they are not clear and therefore are not useful in a clear oil as claimed by Applicants.

Finally, Wester uses more than 50% polyunsaturated fatty acids (PUFAs) in the sterol fatty acid ester composition. Specifically, Wester teaches using more than 50% PUFAs, preferentially 60%, and more preferred, more than 65% PUFAs because of the texturing properties, and cloudy appearance when obtained when less than 50% PUFAs are used. (*See*, Wester, page 5 starting at line 5.) One reading Wester would not be motivated to use anything other than more than 50% MUFAs because only by using more than 50% MUFAs would one be able to get desirable textural properties. Wester, as well as Miettinen and Erickson do disclose the use of sterol fatty acid esters for the same therapeutic use.

Applicants claims recite specifically plant sterol fatty acid esters comprising **more than 50% monounsaturated fatty acids (MUFAs)**. Wester used PUFAs in order to overcome problems with solubility of the plant sterol esters in oil. As detailed in their specification, Applicants wanted to avoid the use of PUFAs because of the problems with PUFAs, such as

negative impact on shelf life and because PUFAs can lower “good” cholesterol in addition to “bad” cholesterol. As Applicants recite in their specification:

In an effort to overcome some to the problems associated with low solubility, PCT published application WO 99/56558 proposes sterol fatty acid esters wherein more than 50% of the fatty acid moieties are polyunsaturated fatty acids (“PUFAs”). The application proposes the use of these compounds in foods and capsules. However, PUFAs have poor oxidative stability, which leads to more rapid degradation of the sterol ester compositions. Because of the instability of these compounds, their use in food products leads to food products with a shorter shelf-life. Additionally, although PUFAs have been shown to lower overall serum cholesterol levels, PUFAs also lower the “good” cholesterol (HDL) in addition to the “bad” cholesterol (LDL).

Specification, page, lines 17-24.

These references do not teach or suggest Applicants’ claimed invention. At best, combination of these references may have made Applicants’ claimed invention *obvious to try*. A determination of obviousness cannot be based on what a skilled person might find obvious to try. Rather, the proper test requires determining what the prior art would have led the skilled person to do. While the Examiner points out that Erickson shows clear oils containing plant sterol esters, the levels of plant sterol esters disclosed in Erickson is only up to 10%, **with a preferred maximum level of 3%**. While the Examiner points out that Miettinen discloses sterol fatty acid esters in oils at levels of 13% and 10-20%, the oils containing sterol fatty acid esters at those levels **are not clear**--those oils are used only in applications such as mayonnaise and margarine, where the clarity of the oil does not matter. While the Examiner points out that Wester discloses sterol fatty acid ester compositions containing more than 50% polyunsaturated fatty acids (PUFAs), this would not have led one to substitute MUFAs for PUFAs. Wester specifically teaches that for good textural properties PUFAs must be used. While it may be *obvious to try* using MUFAs, there is no reasonable expectation of success. Erickson says that plant sterol esters, based on MUFAs are insoluble at levels over 10%, and many plant sterol esters are insoluble at levels over 3%. Miettinen only shows the use of plant sterol esters at levels of over 10% when they are used in non-clear applications, such as margarines or mayonnaise, not clear oils. Wester teaches PUFAs, not MUFAs, should be used for clear oils and good textures. These references do not lead one to an edible oil comprising more than 10% and up to 30% of a sterol fatty acid ester composition, wherien the sterol fatty acid ester composition comprises more than

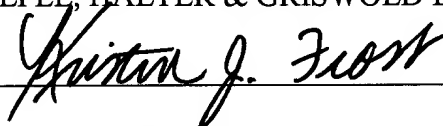
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50% MUFAs; wherein the **edible oil is clear upon addition of the sterol fatty acid ester compositions**, and wherein the **edible containing the sterol fatty acid ester composition remains free of solids at temperatures greater than about 60°F**.

In view of the remarks made herein, Applicants believe this application is in condition for allowance. A timely notice to that effect is respectfully requested.

Respectfully submitted,

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